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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,045	07/24/2006	Ayako Hashimoto	01197.0277	8787

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
12/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,045	HASHIMOTO ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group II in the reply filed on July 30, 2009 is acknowledged.

Claims 1-4 as currently amended are prosecuted with compound of claim 2 and myocardial infarction as the elected species.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating insufficient development and regeneration of blood vessel and various diseases cause by ischemia, does not reasonably provide enablement for *preventing* insufficient development and regeneration of blood vessel and various diseases cause by ischemia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims.

Please note that when insufficient development and regeneration of blood vessel and various diseases cause by ischemia has occurred, any *de novo* prevention cannot be made. Any prevention of the future insufficient development and regeneration of blood vessel and various diseases cause by ischemia is considered a maintenance intervention which is "treatment" of a person in need thereof. It is recommended that the term "prevention" be deleted.

It is unclear what is the scope of claim 4 under "insufficient development and regeneration of blood vessel and various diseases cause by ischemia" to including various organ damages accompanied by diabetes mellitus. Is the organ damages caused by diabetes or by ischemia or both ? Please note that diabetes is ordinarily not an ischemic disorder. Therefore, claim 4 is broadening of claim 3 (objection under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim). In addition, organ damage in diabetes if not *exclusively* resulted from ischemia, is not treatable by increasing blood vessel since the etiology is not lacking of blood vessel. Please note that there is

insufficient description as well as enablement as to how such damage is treatable through angiogenesis.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al. US 5,656,642 (cited on 1449) in view of Orito et al. Azevedo et al. and Zhou et al. supplemented with Sumi et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

Fujioka et al. '642 disclosed the claimed compound being used for treating disorders that requires vasodilating. Specifically, compounds embraced by the instant claims are found in the generic formula (I) and guided by the explicit examples found in table 10 at col. 105, example 46, 52; col. 107, example 57; col. 108, example 60; col. 131 example 142; col. 143-145, examples 183, 186, 187; col. 147, example 193; col. 164-165, examples 254, 257 etc. together with activity in table 12.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art is that the utility of the disclosed compounds is for vasodilation and not enhancing angiogenesis. It is well recognized in the art that both the Fujioka et al. '642 compound (example 193 OPC-28326) and other vasodilator such as prazosin function analogously on the blood vessel (see Orito et al. p.607-610). Vasodilators such as prazosin not only caused vasodilation but also simultaneously affect the tissue to induce angiogenesis (see Azevedo et al. or Zhou et al. whole references).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the above references would be motivated to employ the Fujioka et al. compounds for enhancing angiogenesis because it is the innate nature of such compounds to simultaneously having the affect of inducing angiogenesis and a compound cannot be separated from its innate nature.

The Sumi et al. reference, although published after the filing date, provided factual support for the well known innate nature that the Fujioka et al. compounds function simultaneously as vasodilator and augments ischemia induced angiogenesis.

4. Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,656,642 in view of Orito et al. Azevedo et al. and Zhou et al. supplemented with Sumi et al.

The same rational for the finding of prima facie obviousness as delineated in section 3 is also applicable and hereby incorporated by reference.

The instant application is commonly assigned as the '642 but is not a divisional of the '642 application. Applicants are urged to consult the web site:

www.cabic.com/ejc/BCPCP100802/RHillDP.ppt

for guidelines of obviousness type double patenting and the decision Pfizer Inc. v. Teva Pharma. 86 USPQ2d 1001.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Dec. 3, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625